Remarks

Reconsideration and withdrawal of the rejections of the claims, in view of the remarks presented herein, is respectfully requested.

The Office Action Summary indicates that claims 4, 7-19, 21, 23-25, 27-41 and 44 are withdrawn from consideration. Claims 21, 23-25 and 27-43 are cancelled, and claims 1, 7, 20 and 22 amended. The pending claims are claims 1-20, 22, 26 and 44.

The amendments to the claims are fully supported by the specification as filed. No new matter has been added by way of these amendments.

Election of Species

At page 3 of the Office Action, the Examiner indicates that the Election of Species Requirement mailed March 6, 2006 is final. In the Election of Species Requirement, the Examiner asserted that Applicants' claims are directed, *inter alia*, to the following allegedly patentably distinct species under 35 U.S.C. § 121:

1. Prosthesis

a) annuloplasty ring (FIG. 2);

b) annuloplasty band (FIG. 3);

c) prosthetic heart valve sewing ring;

d) mechanical heart valve (FIG. 4); and

e) stented bioprosthetic valve (FIG. 5).

In a Response to Election of Species Requirement and Preliminary Amendment filed April 26, 2007 (the "Response"), Applicants provisionally elected, with traverse, *inter alia*, species (a) "annuloplasty ring" from 1. Prosthesis. As argued in the Response, Applicants' resubmit that claim 1 of the above-identified application is a generic claim. In particular, claim 1 is directed to a "sewing prosthesis," which as disclosed in the specification at paragraph includes annuloplasty bands, annuloplasty rings, prosthetic heart valve sewing rings and cuffs (page 3, line 29-page 4, line 1). See also page 1, lines 12-14, wherein it is disclosed that "heart valve sewing prostheses are suturable prosthetic

devices that can be implanted in hearts to support of replace the function of the native heart valve." Thus, it is clear that claim 1 is a generic claim that links at least species 1(a)-1(c). "Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR §1.141." M.P.E.P. § 809.02. Reconsideration of the withdrawal of claims 4, 7-19 and 44 is therefore respectfully requested.

The 35 U.S.C. § 103(a) rejection of the claims

The Examiner rejected claims 1-2, 5-6, 20, 22, 26 and 42-43 under 35 U.S.C. §103(a) as being unpatentable over Woo *et al.* (U.S. Patent No. 6,761,736) in view of Carpentier *et al.* (U.S. Patent No. 4,055,861) and Kinlen *et al.* (U.S. Patent No. 6,228,492) or Kuhn *et al.* (U.S. Patent No. 4,775,317 [*sic*]; Applicants' assume the Examiner intended to refer to U.S. Patent No. 4,975,317). In particular, the Examiner asserts that "design and engineering considerations" would have motivated one of ordinary skill in the art to combine the teachings of Woo *et al.* and Carpentier *et al.* so as to arrive at the present invention. As this rejection may be maintained with respect to the pending claims, it is respectfully traversed.

As amended, the claims are directed to an implantable heart valve sewing prosthesis comprising a ring shaped body having a blood contacting external surface including an intrinsically conductive polymer having a resistivity of less than about 2000 ohms per square; and to an annuloplasty prosthesis for implanting in a heart valve annulus in a patient, the annuloplasty prosthesis comprising a ring shaped body comprising a blood contacting external surface comprising an intrinsically conductive polymer.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation either in the cited references themselves or in the knowledge generally available to an art worker, to modify the

reference or to combine reference teachings so as to arrive at the claimed invention. Second, the art must provide a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claim limitations. M.P.E.P. § 2143. The teaching or suggestion to arrive at the claimed invention and the reasonable expectation of success must be found in the prior art, not in Applicant's disclosure. M.P.E.P. § 2143 citing with favor *In re* Vaeck, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

Woo *et al.* disclose that medical articles, such as implantable prostheses, for example, a heart valve prosthesis with leaflets, an orifice ring, *etc.*, can be "improved" when the polymer substrate components of such devices are covered with a diamond-like carbon coating (column 2, lines 48-51; abstract; FIGs. 1-4; column 8, line 34-column 11, line 62). Woo *et al.* disclose that a number of different polymer substrates can be coated with diamond-like carbon (hereinafter referred to as "DLC") in the preparation of such devices, including both flexible and rigid synthetic polymers (column 8, lines 31-53). In a section of the Woo *et al.* document having the heading "Polymer Substrates," conductive polymers, *e.g.*, doped polymers of poly (sulfur nitride), polyacetylene, poly (p-phenylene), poly (phenylene sulfide) and polypyrrole, are also listed (column 8, lines 53-56). However, Applicants' respectfully request that the Examiner consider that it is known in the art that DLC coatings are useful for *insulating* substrates from electrical current. See, for example, Kakuta *et al.*, Proceedings of the 26th Annual International Conference of the IEEE EMBS, 2454-2457 (2004) (a copy in enclosed), wherein it is disclosed that a "remarkable" property of DLC is its "high electrical resistivity" (page 2454, second column). Hence, Woo *et al.*'s disclosure of a device made from any of a number of polymer substrates that are coated with DLC does not disclose or suggest an implantable heart valve sewing prosthesis comprising a ring shaped body having an external surface including an intrinsically conductive polymer having a resistivity of less than about 2000 ohms per square, or an annuloplasty prosthesis for implanting in a heart valve annulus in a patient, the annuloplasty prosthesis comprising a ring shaped body

comprising an intrinsically conductive polymer. Therefore, the pending claims are not obvious in view of Woo *et al.*

Carpentier *et al.* do not remedy the deficiencies of Woo *et al.* Carpentier *et al.* disclose a support for a natural human heart valve that consists of an annular or part annular semi-rigid frame, which frame can be covered by a textile sheath (abstract). Carpentier *et al.* disclose that the device can be made of polyesters such as poly(ethylene terephthalate) or poly (glycol terephthalate), polyamides such as nylon 6--6, nylon 11 or nylon 12, polyolefins, polypropylene, fluorinated polymers such as polytetrafluoroethylene, or polyvinyl chloride (column 3, lines 39-45). Carpentier *et al.* further disclose that the textile sheath can be (i) produced from a woven fabric, *e.g.*, a napped fabric or a cut velour; (ii) a knitted or braided sleeve; or (iii) made of a non-woven fabric (column 3, lines 15-18). However, there is nothing in Carpentier *et al.* that teaches or suggests an implantable heart valve sewing prosthesis comprising a ring shaped body having an external surface including an intrinsically conductive polymer having a resistivity of less than about 2000 ohms per square, or an annuloplasty prosthesis for implanting in a heart valve annulus in a patient, the annuloplasty prosthesis comprising a ring shaped body comprising an intrinsically conductive polymer. Therefore, the pending claims are not obvious in view of Carpentier *et al.*

Kinlen *et al.* do not remedy the deficiencies of Woo *et al.*, either alone or in combination with Carpentier *et al.* Kinlen *et al.* disclose a process for preparing fibers containing intrinsically conductive polymers (referred to by Kinlen *et al.* as "ICPs"). Kinlen *et al.* disclose that their fibers may be useful in a variety of applications (column 12, lines 32-34). However, there is nothing in Kinlen *et al.* that discloses or suggests an implantable heart valve sewing prosthesis or an annuloplasty prosthesis, let alone the invention as presently claimed.

Kuhn *et al.* do not remedy the deficiencies of Woo *et al.*, either alone or in combination with Carpentier *et al.* and/or Kinlen *et al.* Kuhn *et al.* disclose the preparation of electrically conductive textile materials. However, there is nothing in

Khun *et al.* that discloses or suggests an implantable heart valve sewing prosthesis or an annuloplasty prosthesis, let alone the invention as presently claimed.

It is respectfully submitted that *prima facie* obviousness has not been established. As discussed above, the cited art does not teach or suggest all the limitation of the pending claims. Moreover, at page 3 of the Office Action, the Examiner concedes that Woo *et al.* do not disclose specific structural arrangement of the subelements of the annuloplasty ring. Furthermore, because Woo *et al.* disclose devices that when implanted have an electrically non-conductive material in direct contact with host tissue, Woo *et al.* actually *teach away* from the claimed invention. Therefore, one of ordinary skill in the art would not be motivated to combine the teachings of the cited art so as to arrive at the presently claimed invention. Hence, the claims of the present invention are distinct from the cited art. Withdrawal of the 35 U.S.C. §103(a) rejection of the claims is therefore proper and respectfully requested.

Conclusion

Applicants' respectfully submit that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' attorney (763-391-9634) to facilitate prosecution of this application.

Please charge any required fees or credit any overpayments to Deposit Account No. 13-2546.

Respectfully submitted,

Date: 20 August 2007

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